AMENDMENTS TO THE CLAIMS

1-15. (CANCELED)

16. (CURRENTLY AMENDED) An oral dosage form comprising:

(a) an effective amount of an alkalizing agent; and

(b) multiparticulates wherein said multiparticulates comprise (i) azithromycin, and (ii) ~~An oral dosage form of Claim 15 wherein said carrier is~~ a wax, a glyceride or a mixture thereof.

17. (ORIGINAL) An oral dosage form of Claim 16 wherein said wax is a synthetic wax, microcrystalline wax, paraffin wax, Carnauba wax, beeswax or a mixture thereof.

18. (ORIGINAL) An oral dosage form of Claim 16 wherein said glyceride is a glyceryl monooleate, glyceryl monostearate, glyceryl palmitostearate, polyethoxylated castor oil derivatives, hydrogenated vegetable oils, glyceryl behenate, glyceryl tristearate, glyceryl tripalmitate or a mixture thereof.

19. (CURRENTLY AMENDED) An oral dosage form of Claim 18 wherein said glyceride comprises ~~a mixture of~~ glyceryl monobehenate, glyceryl dibehenate, ~~and~~ glyceryl tribehenate or a mixture thereof.

20. (CANCELED)

21. (ORIGINAL) An oral dosage form of Claim 16 further comprising a dissolution enhancer.

22. (ORIGINAL) An oral dosage form of Claim 21 wherein said dissolution enhancer comprises an alcohol, a surfactant, an ether-substituted cellulosics, a sugar, a salt, an amino acid or a mixture thereof.

23. (ORIGINAL) An oral dosage form of Claim 22 wherein said dissolution enhancer

comprises a surfactant selected from the group consisting of poloxamers, docusate salts, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, sorbitan esters, alkyl sulfates, polysorbates and polyoxyethylene alkyl esters.

24. (ORIGINAL) An oral dosage form of Claim 23 wherein said dissolution enhancer comprises a poloxamer.

25. (CURRENTLY AMENDED) An oral dosage form Claim 24 wherein the poloxamer comprises poloxamer 407. ~~comprising:~~
~~(a)an effective amount of an alkalizing agent; and~~
~~multiparticulates wherein said multiparticulates comprise (i) azithromycin, (ii) a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate, and (iii) a poloxamer.~~

26. (CURRENTLY AMENDED) An oral dosage form of Claim 25 wherein the ~~poloxamer comprises poloxamer 407~~ alkalizing agent comprises an aluminum salt, a magnesium salt, a calcium salt, a bicarbonate, a phosphate, a metal hydroxide, a metal oxide, N-methyl glucamine, arginine, an arginine salt, an amine or a combination thereof.

27. (ORIGINAL) An oral dosage form of Claim 26 wherein the alkalizing agent comprises tribasic sodium phosphate and magnesium hydroxide.

28. (CURRENTLY AMENDED) An oral dosage form of Claims ~~1, 2, 25-27~~ 26 further comprising about 250 mgA to about 7 gA of azithromycin.

29. (ORIGINAL) An oral dosage form of Claim 28 further comprising about 1.5 gA to about 4 gA of azithromycin.

30. (ORIGINAL) An oral dosage form of Claim 28 further comprising 1.8 to 2.2 gA of azithromycin.

31. (ORIGINAL) An azithromycin oral dosage form, comprising:

(a) at least about 200 mg of tribasic sodium phosphate; and

(b) multiparticulates, wherein said multiparticulates comprise (i) azithromycin, (ii) a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate, and (iii) poloxamer 407, and wherein said dosage form contains about 1.5 gA to about 4 gA of azithromycin.

32. (ORIGINAL) An oral dosage form of Claim 31, further comprising at least about 100 mg of magnesium oxide.

33. (ORIGINAL) An oral dosage form of Claim 31, comprising:

(a) 300 mg to 400 mg of tribasic sodium phosphate;

(b) 200 mg to 300 mg of magnesium hydroxide; and

(c) multiparticulates, wherein said multiparticulates comprise (i) azithromycin, (ii) a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate, and (iii) poloxamer 407,

and wherein said dosage form contains about 1.5 gA to about 4 gA of azithromycin.

34. (ORIGINAL) An oral dosage form of Claims 31-33 further comprising 1.8 to 2.2 gA of azithromycin.

35. (ORIGINAL) An oral dosage form of Claim 34 wherein said azithromycin is azithromycin dihydrate.

36. (CURRENTLY AMENDED) An oral dosage form of Claims ~~1, 2, 25-27, 31-33 and 35~~ 16 wherein said azithromycin is azithromycin dihydrate.

37. (CURRENTLY AMENDED) An oral dosage form of Claims ~~1, 2, 25-27, 31-33 and 35~~ 26 wherein said azithromycin is at least 70 wt% crystalline.

38. (CURRENTLY AMENDED) An oral dosage form of Claims ~~1-11, 25-27, 31-33 and 35~~ 26 wherein said oral dosage form is a powder for oral suspension, a unit dose packet, an oral suspension, a tablet or a capsule.

39 – 48. (CANCELED)

49. (CURRENTLY AMENDED) A method for reducing the frequency of gastrointestinal side effects, associated with administering azithromycin to a mammal, comprising contiguously administering oral dosage form of claim 16 ~~azithromycin and an effective amount of alkalizing agent~~ to said mammal wherein the frequency of gastrointestinal side effects is reduced as compared to the frequency experienced when administering an equal dose of azithromycin without said alkalizing agent.

50. (ORIGINAL) A method of Claim 49 wherein said mammal is a human.

51. (ORIGINAL) A method of Claim 50 further comprising administering between about 250 mgA and about 7 gA of azithromycin to said human.

52. (ORIGINAL) A method of Claim 51 wherein the azithromycin is administered in a single dose.

53. (ORIGINAL) A method of Claim 52 further comprising administering between about 1.5 and about 4 gA of azithromycin.

54. (ORIGINAL) A method of Claim 52 further comprising administering between about 1.5 and about 3 gA of azithromycin.

55. (ORIGINAL) A method of Claim 52 further comprising administering between 1.8 and 2.2 gA of azithromycin to said human in a single dose.

56. (ORIGINAL) A method of Claim 50 further comprising administering between 30

mgA/kg and 90 mgA /kg of azithromycin to a human, wherein said human is a child weighing 30 kg or less.

57. (ORIGINAL) A method of Claim 56 wherein the azithromycin is administered in a single dose.

58. (ORIGINAL) A method of Claim 57 further comprising administering between 45 mgA/kg and 75 mgA /kg of azithromycin to a child weighing 30 kg or less.

59. (ORIGINAL) A method of Claim 57 further comprising administering about 60 mgA/kg of azithromycin to a child weighing 30 kg or less.

60. (CURRENTLY AMENDED) A method of ~~Claims 49-59~~ Claim 49 wherein the alkalizing agent further comprises an aluminum salt, a magnesium salt, a calcium salt, a bicarbonate, a phosphate, a metal hydroxide, a metal oxide, N-methyl glucamine, arginine, an arginine salt, an amine, or a combination thereof.

61. (ORIGINAL) A method of Claim 60 wherein the alkalizing agent comprises tribasic sodium phosphate and magnesium hydroxide.

62. (ORIGINAL) A method of Claim 60 wherein said azithromycin comprises an immediate release form of azithromycin.

63. (ORIGINAL) A method of Claim 60 wherein said azithromycin comprises a sustained release form of azithromycin.

64. (ORIGINAL) A method of Claim 60 wherein said azithromycin comprises azithromycin multiparticulates.

65. (ORIGINAL) A method of Claim 64 wherein said azithromycin multiparticulates comprise:

(a) azithromycin; and

(b) a pharmaceutically acceptable carrier.

66. (ORIGINAL) A method of Claim 65 wherein said carrier is a wax, a glyceride, or a mixture thereof.

67. (ORIGINAL) A method of Claim 66 wherein said wax is a synthetic wax, microcrystalline wax, paraffin wax, Carnauba wax, beeswax, or a mixture thereof.

68. (ORIGINAL) A method of Claim 66 wherein said glyceride is a glyceryl monooleate, glyceryl monostearate, glyceryl palmitostearate, polyethoxylated castor oil derivatives, hydrogenated vegetable oils, glyceryl monobehenate, glyceryl dibehenate, glyceryl tribehenate, glyceryl tristearate, glyceryl tripalmitate, or a mixture thereof.

69. (ORIGINAL) A method of Claim 66 wherein said glyceride comprises a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate.

70. (ORIGINAL) A method of Claim 65 further comprising a dissolution enhancer.

71. (ORIGINAL) A method of Claim 66 further comprising a dissolution enhancer.

72. (ORIGINAL) A method of Claim 71 wherein said dissolution enhancer comprises an alcohol, a surfactant, an ether-substituted cellulosics, a sugar, a salt, an amino acid or a mixture thereof.

73. (ORIGINAL) A method of Claim 72 wherein said dissolution enhancer comprises a surfactant selected from the group consisting of poloxamers, docusate salts, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, sorbitan esters, alkyl sulfates, polysorbates and polyoxyethylene alkyl esters.

74. (ORIGINAL) A method of Claim 72 wherein said dissolution enhancer comprises a

poloxamer.

75. (ORIGINAL) A method for reducing the frequency of gastrointestinal side effects, associated with administering azithromycin to a human, comprising contiguously administering azithromycin multiparticulates and an effective amount of alkalizing agent to said human, wherein said multiparticulates comprise (i) azithromycin, (ii) a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate, and (iii) a poloxamer, wherein the frequency of gastrointestinal side effects is reduced as compared to the frequency experienced when administering an equal dose of azithromycin without said alkalizing agent.

76. (CURRENTLY AMENDED) A method of treating a bacterial or protozoal infection in a mammal in need thereof comprising ~~contiguously~~ administering to said mammal a single dose of an oral dosage form of claim 16. ~~wherein said oral dosage form comprises:~~

~~a) azithromycin; and~~

~~b) an effective amount of an alkalizing agent.~~

77. (ORIGINAL) A method of Claim 76 wherein said mammal is a human.

78. (ORIGINAL) A method of Claim 77 further comprising administering between about 250 mgA and about 7 gA of azithromycin to said human.

79. (ORIGINAL) A method of Claim 78 wherein the azithromycin is administered in a single dose.

80. (ORIGINAL) A method of Claim 79 further comprising administering between about 1.5 and about 4 gA of azithromycin to said human.

81. (ORIGINAL) A method of Claim 79 further comprising administering between about 1.5 and about 3 gA of azithromycin to said human.

82. (ORIGINAL) A method of Claim 79 further comprising administering 1.8 gA to 2.2 gA of azithromycin to said human.

83. (ORIGINAL) A method of Claim 77 further comprising administering between 30 mgA/kg and 90 mgA /kg of azithromycin to said human, wherein said human is a child weighing 30 kg or less.

84. (ORIGINAL) A method of Claim 77 wherein the azithromycin is administered in a single dose.

85. (ORIGINAL) A method of Claim 84 further comprising administering between 45 mgA/kg and 75 mgA /kg of azithromycin to a child weighing 30 kg or less.

86. (ORIGINAL) A method of Claim 84 further comprising administering 60 mgA/kg of azithromycin to a child weighing 30 kg or less.

87. (ORIGINAL) A method of Claims 76-86 wherein the alkalizing agent further comprises an aluminum salt, a magnesium salt, a calcium salt, a bicarbonate, a phosphate, a metal hydroxide, a metal oxide, N-methyl glucamine, arginine, an arginine salt, an amine, or a combination thereof.

88. (ORIGINAL) A method of Claim 87 wherein the alkalizing agent comprises tribasic sodium phosphate.

89. (ORIGINAL) A method of Claim 88 wherein the alkalizing agent further comprises magnesium hydroxide.

90. (ORIGINAL) A method of Claim 87 wherein said azithromycin comprises an immediate release form of azithromycin.

91. (ORIGINAL) A method of Claim 87 wherein said azithromycin comprises a sustained release form of azithromycin.

92-107. (CANCELED)

108. (CURRENTLY AMENDED) Azithromycin multiparticulates comprising:

(a) azithromycin;

(b) a surfactant; and

(b) a ~~pharmaceutically acceptable carrier~~ wax, a glyceride, or a mixture thereof, wherein at least 70% of the azithromycin is crystalline.

109. (ORIGINAL) A multiparticulate of Claim 108 wherein said surfactant is selected from the group consisting of poloxamers, docusate salts, polyoxyethylene alkyl ethers, hylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, sorbitan esters, alkyl sulfates, polysorbates and polyoxyethylene alkyl esters.

110. (ORIGINAL) A multiparticulate of Claim 109 wherein said surfactant comprises a poloxamer.

111. (CENCELED)

112. (CURRENTLY AMENDED) A multiparticulate of Claim ~~111~~ 108 wherein said wax is a synthetic wax, microcrystalline wax, paraffin wax, Carnauba wax, beeswax, or a mixture thereof.

113. (CURRENTLY AMENDED) A multiparticulate of Claim ~~111~~ 108 wherein said glyceride is a glyceryl monooleate, glyceryl monostearate, glyceryl palmitostearate, polyethoxylated castor oil derivatives, hydrogenated vegetable oils, glyceryl monobehenate, glyceryl dibehenate, glyceryl tribehenate, glyceryl tristearate, glyceryl tripalmitate, or a mixture thereof.

114. (ORIGINAL) A multiparticulate of Claim 113 wherein said glyceride comprises a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate.